

**Notice of Allowability**

Application No.

10/784,986

Applicant(s)

HIRANO ET AL.

Examiner

Kagnew H. Gebreyesus

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 01/17/2007.
2. ☒ The allowed claim(s) is/are 1-4, 6, 8, 9 and 11-13.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                                |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                        |
|  | 9. <input type="checkbox"/> Other _____  |

*Kagnew H. Gebreyesus*

### **DETAILED ACTION**

Applicant's response on January 17, 2007 to the Advisory Action dated June 01, 2006 and January 12, 2007 is acknowledged. Applicants filed a revised Appeal brief January 17, 2007.

#### ***Status of Claims:***

Claims 1-6, 8-13 are pending. Claims 10, 11, 12, 13 are new. Claim 7 is canceled. Claims 1-4, and 11 were allowable. Claims 5, 6, 12 and 13 were rejected in the Final Office Action dated February 16, 2006.

#### ***Withdrawn- Claim Rejections - 35 USC § 112***

Claims 5 and 10 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been withdrawn following Applicant's cancellation of these claims.

#### ***Withdrawn - Claim Rejections - 35 USC § 103***

Claims 8, 9, 12 and 13 were rejected under 35 USC 103(a) as being unpatentable over Kikuchi et al. in view of and Gunji et al. Applicant's arguments has been considered and found to be persuasive. This rejection is hereby withdrawn because claims 8 and 12 are drawn to microorganisms comprising a polynucleotide encoding a lysine decarboxylase gene isolated from *Methylophilus* bacteria.

The prior art teaches at least two forms of lysine decarboxylase genes (CadA and Ldc) from *E. coli*. However the prior art does not disclose the specific lysine

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decarboxylase gene isolated from any *Methylophilus* bacteria. Therefore a person of ordinary skill in the art that desires to practice the invention in the instant application would have to first identify and disrupt the gene encoding the isoform that results in accumulation of lysine in *Methylophilus*. While this experimentation can be tried by an ordinary person skilled in the art, such experimentation entails, ascertaining the existence of a lysine decarboxylase(s) in *Methylophilus* bacteria, deciphering the specific isoform(s) that can result in accumulation of L-lysine, disrupting it in view of practicing the instant invention. Given that the standard for a rejection under 35 USC 103 does not encompass experimentations that are "obvious to try", the rejection of claims 8, 9, 11-13 drawn to *Methylophilus* bacteria comprising the polynucleotide that encodes the polypeptide of SEQ ID NO: 4, and the method of using said recombinant strains to produce L-lysine is hereby withdrawn.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Shelly Cermak on June 11, 2007.

See attached.

Conclusion: Claims 1-4, 6,8, 9, 11-13 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnew H Gebreyesus  
Examiner  
Art Unit 1656  
6/5/2007.

  
KATHLEEN KERR BRAGDON, PH.D.  
SUPERVISORY PATENT EXAMINER

### EXAMINER'S AMENDMENT

1. An isolated protein selected from the group consisting of:  
(A) a protein which has the amino acid sequence of SEQ ID NO: 4; and  
(B) a protein which has the amino acid sequence of SEQ ID NO: 4 including substitution, deletion, insertion or addition of one to 20 amino acid residues and has lysine decarboxylase activity.
2. An isolated protein selected from the group consisting off  
(A) a protein which has the amino acid sequence of SEQ ID NO: 4; and  
(B) a protein which has the amino acid sequence of SEQ ID NO: 4 including substitution, deletion, insertion or addition of one to 10 amino acid residues and has lysine decarboxylase activity.
3. An isolated DNA encoding a protein selected from the group consisting off  
(A) a protein which has the amino acid sequence of SEQ ID NO: 4; and  
(B) a protein which has the amino acid sequence of SEQ ID NO: 4 including substitution, deletion, insertion or addition of one to 20 amino acid residues and has lysine decarboxylase activity°
4. An isolated DNA encoding a protein selected from the group consisting of:  
(A) a protein which has the amino acid sequence of SEQ ID NO: 4; and  
(B) a protein which has the amino acid sequence of SEQ ID NO: 4 including substitution, deletion, insertion or addition of one to 10 amino acid residues and has lysine decarboxylase activity.
5. Cancelled.
6. The DNA of claim 3, which is isolated from the genome of a Methylophilus bacterium.
7. Cancelled.
8. A Methylophilus bacterium which produces L-lysine, wherein a polynucleotide on the genome is disrupted, wherein said polynucleotide is the DNA of claim 3, and thereby the intracellular lysine decarboxylase activity is reduced or eliminated.
9. A method for producing L-lysine, comprising the steps of culturing the Methylophilus bacterium of claim 8 in a medium containing methanol as a major carbon source resulting in accumulation of L-lysine in culture, and collecting the L-lysine from the culture.

10. Cancelled.

11. The DNA of claim 4, which is isolated from the genome of a Methylophilus bacterium.

12. A Methylophilus bacterium which produces L-lysine, wherein a polynucleotide on the genome is disrupted, wherein said polynucleotide is the DNA of claim 4, and thereby the intracellular lysine decarboxylase activity is reduced or eliminated.

13. A method for producing L-lysine, comprising the steps of culturing the Methylophilus bacterium of claim 12 in a medium containing methanol as a major carbon source resulting in accumulation of L-lysine in culture, and collecting the L-lysine from the culture.